A copy of the database is available upon an email request to montague.brian@epa.gov. Further information is also available in Support Document #32.

Ecological Incident Information System: After a field has been treated with pesticides, wildlife may be exposed to these chemicals by several routes. When the exposure is high relative to the toxicity of the pesticide, wildlife may be killed or visibly incapacitated. Many of these ecological incidents are probably not observed or reported, but when they are reported to the proper authority (usually a state agency), they are investigated and an incident report is generated.

In 1992, the Agency created a database called The Ecological Incident Information System (EIIS) to store information extracted from these incident reports. (Documentation is provided in Support Document #22.) The two primary sources of incident reports are pesticide registrants and government agencies. Under section 6(a)(2) of the pesticide law FIFRA, pesticide registrants or manufacturers are required to report to EPA any information related to known adverse effects to the environment caused by their registered pesticides.

The second major source of information is investigative reports which are voluntarily submitted to the Agency from state and other federal agencies that oversee agriculture, wildlife, natural resources, and environmental quality. Diagnostic reports are also obtained from the National Wildlife Health Institute (USGS), the Patuxent Wildlife Research Center (USGS), the Southwest Wildlife Cooperative Disease Study, and state wildlife forensic laboratories. Information is also extracted from accounts of ecological incidents reported in newspapers and reliable internet sources.

Information in EIIS records, if available, include the data and location of the incident, type and magnitude of affects observed in various species, use(s) of pesticides known or suspected of contributing to the incident, and the results of any chemical residue and cholinesterase activity analyses conducted during the incident investigation.

Environmental Fate Database: OPP collects and reviews a variety of environmental fate studies submitted by pesticide manufacturers in support of the registration of pesticide products. After reviewing the data in these studies, OPP scientists summarize the information in DERs, REDs, and other reports.

Check on monitoring?

In 2000, OPP initiated the development of a pesticide environmental fate database which will allow the user to search and view the data, query the fate database, and print reports that are found in these summary reports. Presently, this database contains environmental fate and transport data for about 250 pesticide active ingredients. OPP Program plans to complete the initial version of this database by the end of 2003.

d. Technology Teams and Science Policy Panel (To be completed.)

3. Internal Peer Review Mechanisms

a. Data Evaluation Records

All Data Evaluation Records (DERs) are peer reviewed internally at the branch level by another EFED scientist with the appropriate expertise. After the branch-level peer reviewer signs off on the final DER, it is sent to the EFED Tracking Team who forwards it the appropriate risk management division.

b. Risk Assessments and Risk Characterizations

All risk assessments and risk characterizations are reviewed within a task team consisting of interdisciplinary scientists. After the task team reviews these documents, they are peer reviewed within the branch or in another EFED branch by a scientist with appropriate expertise.

Following branch-level review, divisional peer review is conducted by the Risk Assessment and Risk Characterization Review Panel (Review Panel) which consists of interdisciplinary scientists who peer review all major risk assessments and risk characterizations for new chemicals and for reregistration actions. This Panel is an important internal peer review mechanism and is composed of senior scientists in the division. In addition, FEAD scientists participate as well and provide technical comments on the assessment process in general and as it relates to endangered and threatened species. After panel members have reviewed a specific risk assessment, they meet with scientists, provide feedback, and ask questions concerning the assessment. The Review Panel's comments along with the reviewers' responses to their comments are included in the final documents.

what is major ?

In some cases where the assessments may be controversial, they may be peer reviewed externally by the Scientific Advisory Panel (SAP) or other external advisory group. The SAP is discussed in the next section.

4. External Peer Review and Scientific Advisory Panel

New environmental tools and methodologies and science policies are peer reviewed internally by management. In addition, all significant new science policies and procedures, tools and methodologies are reviewed by the FIFRA Scientific Advisory Panel (SAP), EPA's peer review body for current scientific issues related to pesticides. It is comprised of nationally and internationally recognized scientific experts in toxicology, pathology, environmental biology, and related sciences and are appointed by the Administrator.

For example, the FIFRA SAP has peer reviewed the new tools and methodologies OPP has been working on in its initiative to refine the ecological assessment process for pesticides. This initiative, which began in 1997, was in response to recommendations from a meeting with the SAP in 1996 and built upon previous efforts in the Division. Throughout the development of

this initiative, OPP has returned to the SAP several times to seek comments and recommendations on the progress being made. In some cases, EFED has sought guidance from the SAP on problematic issues and questions before proceeding further. Input from the SAP early in the development of tools and methods is critical to successful implementation of them into the risk assessment process.

III. Basic Terms

The reader is encouraged to review the following terms since their definitions may differ among Agencies.

EEC (Estimated Environmental Concentration) - Estimates of exposure levels of pesticides in aquatic or terrestrial ecosystems.

Ecological Effects Assessment - Characterization of the types of effects a pesticide can produce in an organism.

Ecological Risk Assessment - The process that evaluates the likelihood that adverse ecological effects may occur or are occurring as result of exposure to a stressor.

Exposure - The contact or co-occurrence of a stressor with a receptor.

Environmental Exposure Assessment - The risk quotient calculation, ratio of EEC values to toxicity endpoint.

Environmental Fate - Behavior (i.e. persistence, mobility, volatility, etc.) of the chemical in the environment.

Fate Assessment - Interpretation and integration of fate data and a discussion of how the chemical is likely to behave in the environment.

Hazard - Action or condition that has the potential to cause an undesired effect.

Toxicity Assessment - Evaluation of the intrinsic effects of a stressor.

Level of Concern (LOC) - EPA's interpretative policy used to analyze potential risk to non-target organisms and the need to consider regulatory action.

Risk - The potential or likelihood of causing adverse effects in the environment. Risk is a function of exposure and toxicity.

Risk Characterization - A phase of the ecological risk assessment that integrates the exposure and

stressor response profiles to evaluate the likelihood of adverse ecological effects associated with exposure to a stressor. Lines of evidence and the adversity of effects are discussed.

Risk Quotient (RQ) - A single point estimate of exposure divided by a point estimate of toxicity. It is produced by a screening level or deterministic assessment. Risk quotients are the numerical ratio of estimated environmental concentration to toxicity endpoint.

Toxicity - The quality or condition of being harmful to a living organism and the classification of that harm.

Transport - The movement of the pesticide in the environment.

Uncertainty - Results from a lack of knowledge

Variability - The inherent stochastic heterogeneity of natural variation in a risk estimate

VI. Overview of OPP Screening Level Ecological Risk Assessment Process for Aquatic Life, Wildlife, and Plants

Process flowcharts for the EFED ecological risk assessment processes for the registration of a new chemical and for a reregistration action can be found below in Figures 2 and 3, respectively, on pp. 27 and 28.

A. Problem Formulation

Before the risk assessment process begins, risk assessors and risk managers discuss the potential value of conducting a risk assessment, goals for ecological resources, range of management options, objectives of the risk assessment, the focus, scope and timing of the assessment, and resource availability. The characteristics of an ecological risk assessment are directly determined by agreements reached by risk managers and risk assessors during early planning meetings.

1. Defining the Regulatory Action

Prior to initiation of the risk assessment process, risk managers communicate the nature of the regulatory action with the risk assessors. For risk assessment activities supporting REDs, these communications are initiated with personnel from SRRD. For regulatory actions involving new pesticide active ingredients or new uses of existing active ingredients (FIFRA Section 3 actions), emergency exemptions (FIFRA Section 18 actions), and special local needs uses (FIFRA Section 24c actions) the regulatory communications are initiated with personnel from RD. During this problem formulation phase, risk assesors and risk managers consider the following questions:

- What is the regulatory basis for the requested action under FIFRA and how does that affect the temporal and geographic scope of the impact area of the risk assessment?
- What are the management goals and decisions needed, and how will risk assessment help?
- Are there any policy considerations that everyone should be aware of?
- What precedents are set by similar risk assessments and previous decisions?
- What is the context (the spatial and temporal boundaries) of the assessment (e.g., agricultural use site twice per season - June and July, aquatic habitat adjacent to the use site, etc.)?

2. Aspects of Pesticide Products Not Routinely Considered in the Screening Risk Assessment (To be completed.)

How can these considerations be expanded to explore T+E species related up front?

How can that be expanded to consider T+E species?

Figure 2: EFED Risk Assessment Process for a New Chemical

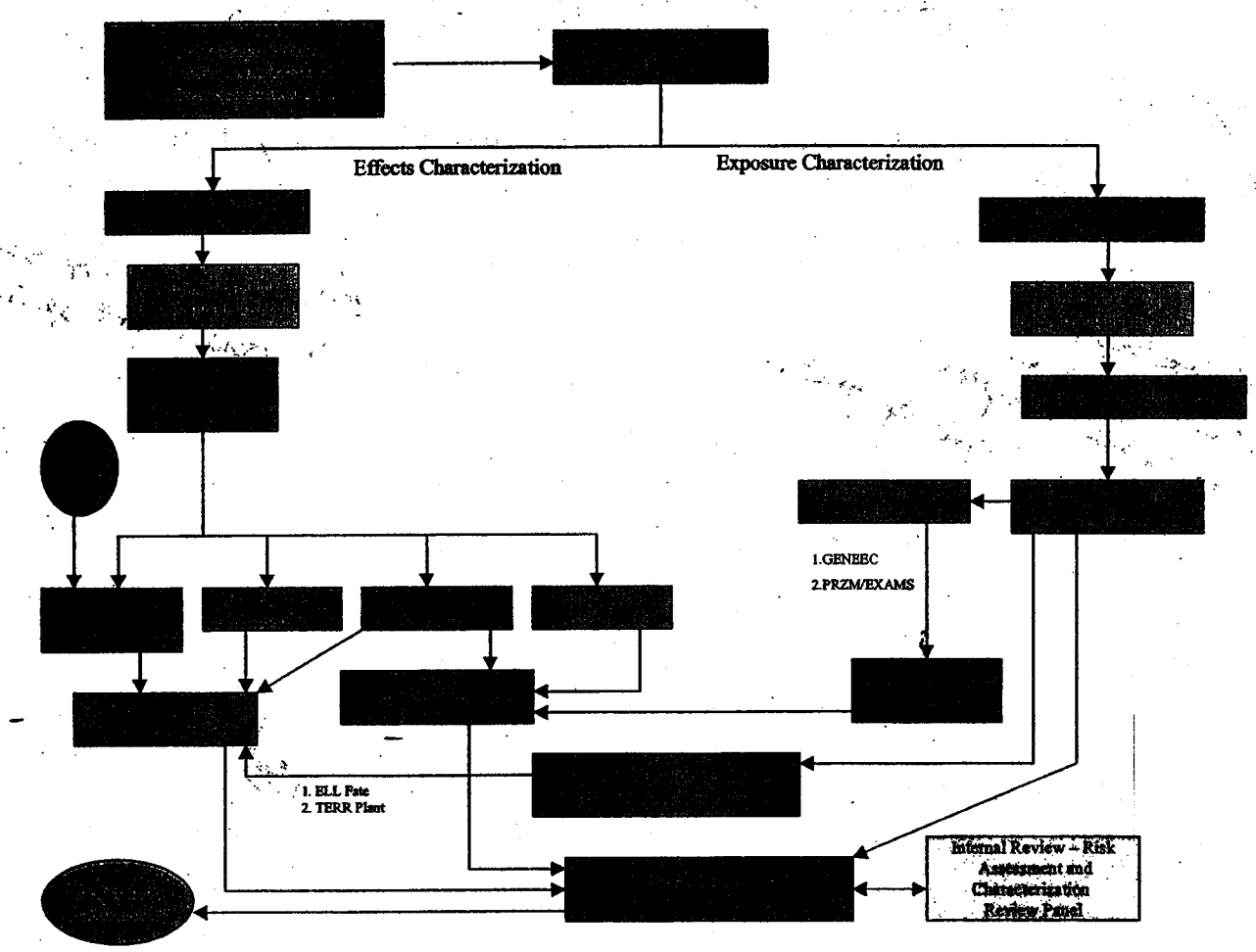
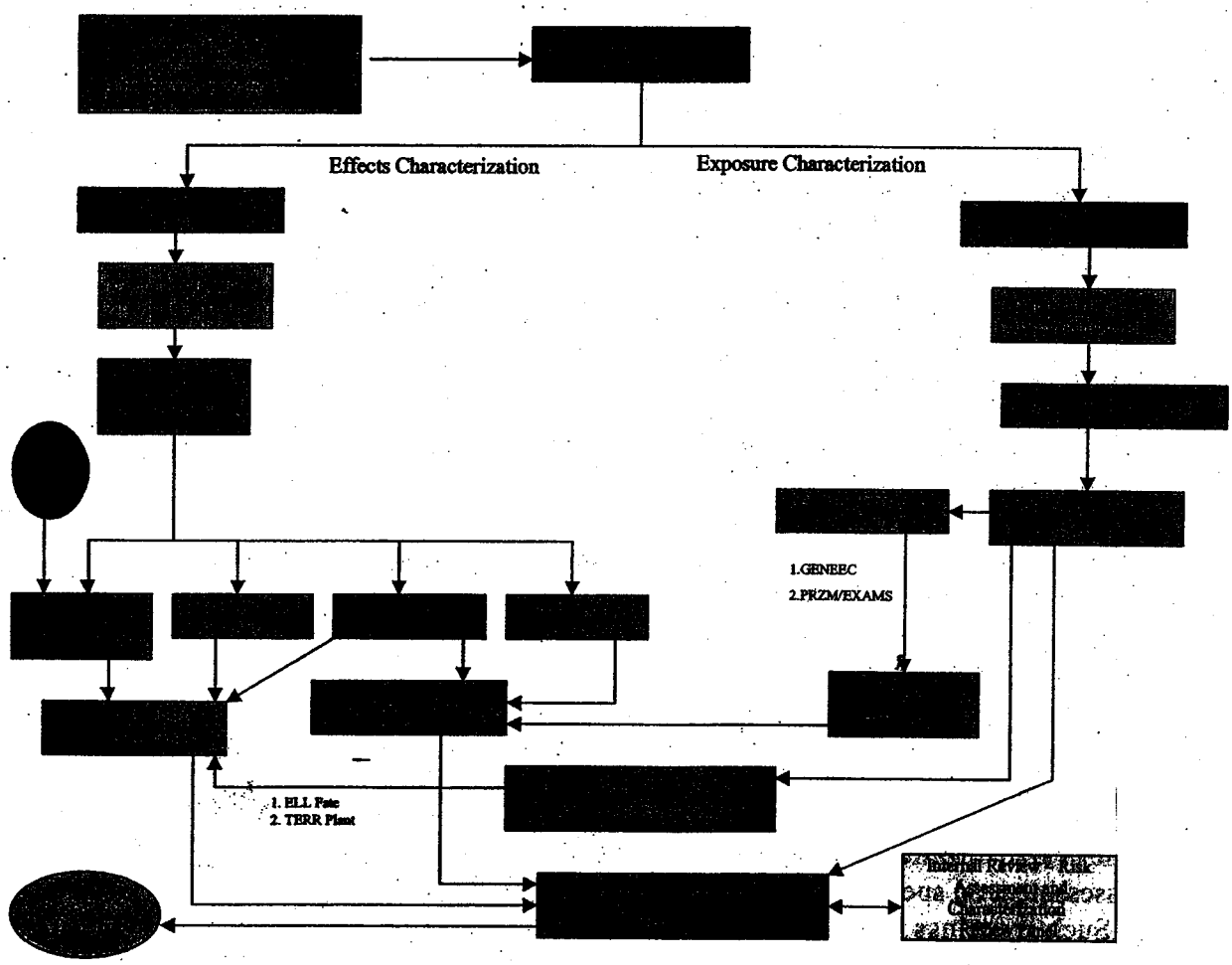


Figure 3: EFED Risk Assessment for a Reregistration Eligibility Decision



3. Pesticide Use Characterization

For each chemical action, product labels provide information on the proposed and/or existing uses of the pesticide. The pesticide label is the legal document that provides the user with instructions for use, use restrictions, and hazard statements. Risk assessors use the information on the product label to define the nature of the pesticide use in the field. Use factors on the label are important for determining input parameters for exposure models and the magnitude of exposure to non-target organisms, including geographic locations most likely to be impacted. Label information crucial to the ecological assessments include:

- Formulation and product purity
- Proposed and/or existing application rates
- Target pest(s) and benefitted crop(s)
- Geographic limitations of use, if any
- Application methods: aerial, ground, foliar, soil surface, soil incorporated, etc.
- Application timing: seasonal, time of day
- Frequency of application, application intervals, and maximum number of applications per season
- Hazard advisory statements: protective measure for wildlife/aquatic habitats, groundwater, etc.

In addition to the information on the label, scientists consult with BEAD and the registrant for information on the following topics:

- Nature of the target pests;
- Geographical distribution of the pests, crop, and market of the pesticide;
- Temporal pattern of the pesticide's use; and
- Any unique aspects to the use of the pesticide under field conditions.

The characterization of pesticide use allows the risk assessors and risk managers to focus the risk assessment on specific use patterns that are representative of a larger variety of use patterns. Such groupings may consider the types of agricultural scenarios, the methods for pesticide application, and commonality of applications rates and timing. In this way, modeling and assessment resources can be concentrated on scenarios that are reasonably and conservatively representative of a larger suite of pesticide use scenarios.

4. Identification of Assessment Endpoints

The Agency Guidelines define assessment endpoints as "explicit expressions of the actual environmental value that is to be protected" which are "operationally defined by an ecological entity and its attributes" (Support Document #7). The ecological entity can be a species, a functional group of species, a community, an ecosystem, or an other entity of importance or

concern. An attribute is the characteristic of the entity that is important to protect and is potentially at risk. The selection of clearly defined assessment endpoints is important because they provide direction and boundaries in the risk assessment for addressing risk management issues of concern. Each assessment endpoint needs one or more "measures of effect", which are changes in the attributes of an assessment endpoint itself or changes in some surrogate test in response to exposure to a pesticide.

The typical assessment endpoints for pesticide ecological risk assessments are reduced survival and reproductive impairment for both aquatic and terrestrial species from both direct acute and direct chronic exposures. These assessment endpoints, while measured at the individual level, provide insight to risks at higher levels of biological organization (populations and community level). If effects to the survival and reproduction of individuals are limited, its assumed that risks at the population and community level will be of minor consequence. However, as the risk of reductions in survival and/or reproduction rates increase, the greater the risk to populations and communities. While, risk managers believe it is useful to quantify these risks at the population and community level, current methods and species specific data on vital rates is lacking to address these questions with meaningful scientific rigor (http://www.epa.gov/oppefed1/ecorisk/index.htm).

5. Measures of Effects and Exposure: The Use of Surrogate Organisms

Rarely are toxicity data available for the species identified in the risk assessment endpoints. In the majority of cases, the screening risk assessment process relies on a suite of toxicity studies performed on a limited number of organisms in the following broad groupings:

- Birds (mallard duck and bobwhite quail)
- Mammals (laboratory rat)
- Freshwater fish (bluegill sunfish, rainbow trout, and fathead minnow)
- Freshwater invertebrates (*Daphnia magna*)
- Estuarine/marine fish (sheepshead minnow)
- Estuarine/marine invertebrates (*Crassostrea virginica* and *Mysidopsis bahia*)
- Terrestrial plants (corn, soybean, carrot (radish or sugar beet), oat (wheat or ryegrass), tomato, onion, cabbage (cauliflower or brussels sprout), lettuce, cucumber)
- Aquatic plants

Within each of these very broad taxonomic groups an acute and chronic toxicity endpoint is selected from the available test data. The selection is made from the most sensitive species tested within that organism group. If additional toxicity data for more species of organisms in a particular group are available, the selection need not be limited to the species listed above, but may be expanded to include data for other species/studies that meet the data quality classification of "supplemental". (See Support Document #1 for discussion of the data classification scheme). Regardless of the extent of data beyond the base set of toxicity studies, the risk assessment relies

on selection of endpoints from the most sensitive species tested in acceptable studies.

Exposures estimated in the screening risk assessment for endangered species are likewise not specific to a given species. Estimates for terrestrial birds and mammals assume generic groupings of food preferences (e.g., obligate insectivores, herbivores, granivores) and generic weight classes.

6. Identification of Data Gaps

There are a variety of reasons for why risk assessments may contain data gaps. One primary reason is that the data were not submitted to the Agency. For ecological effects data, a data gap may exist if the results of a Tier I study triggers testing at the Tier II level for studies that were not conducted. For the environmental fate data, results of laboratory studies, subsequent exposure modeling, and other available information may indicate that the chemical will be present at levels of concern for non-target organisms. This finding may trigger the requirement of a residue monitoring study. Data gaps may also arise if the submitted data are invalid and deviations in the acceptable protocol cannot be fixed; invalid data cannot be used in the assessment. In this case, a new study is required to be conducted using acceptable protocol.

When a data package is received for a new registration, the submissions are reviewed to ensure that the environmental fate and ecological effects data sets are complete for the proposed pesticide use. For actions in which data for the pesticide is already available (e.g., re-registration, new uses of existing chemicals, Section 18s, etc.), the risk assessor reviews the adequacy of existing and new submissions, and previous assessments. In either case, whenever possible, data gaps are noted early on in the risk assessment process and communicated to the risk manager. Data gaps are also addressed as a source of uncertainty in the risk assessment conclusions.

Once data gaps are identified, the risk assessment team must determine whether it is possible to perform the risk assessment. Ideally, a screening level ecological risk assessment is possible when the data submitted on ecological effects and environmental fate of the pesticide are scientifically valid and complete. That is, they meet the Agency's study specific established review criteria as set forth in the SEPs, (Support Document #6). In situations where submitted data are found to be scientifically valid but do not fully comply with the review criteria, professional judgement is used by the risk assessment team to determine the utility of the data for the proposed risk assessment. This latter evaluation may include reference to data quality objectives for specific types of studies, the degree to which adequate documentation is available to evaluate the technical merit of the data, and whether the data are applicable to the assessment endpoints established for the risk assessment.

B. Analysis Phase

1. Exposure Characterization

An exposure characterization provides a quantitative analysis of the critical environmental fate and transport properties of the pesticide. These quantitative expressions of the fate and transport properties, along with the information related to the use of the pesticide and the physical, chemical, and biological conditions of the use sites are used to estimate the potential exposure of plants, wildlife, and aquatic life to pesticide residues in environmental media. This characterization includes information on how often, how long, and the amount of pesticide or degradates of concern to which an organism may be exposed. The exposure characterization is based on environmental fate and transport data as well as modeling and monitoring information.

In order to quantitatively predict the fate and transport of a pesticide once it is introduced into the environment, OPP scientists review laboratory and field studies that measure how pesticides interact with soils, air, sunlight, surface water, and ground water. These studies answer questions about:

- The degradation of the pesticide (how fast and by what means it is degraded in the environment) or how persistent the pesticide is in the environment;
- The breakdown products that result from the degradation processes;
- The mobility or how much of a pesticide or its degradates or metabolites will travel from the application site; these studies predict the potential of the pesticide to volatilize into the atmosphere, move into ground or surface waters, or bind to the soil; and
- How much of a pesticide and its degradates or metabolites will accumulate in the environment.

a. Fate and Transport Data Requirements and Study Evaluation

Certain laboratory and field studies (e.g., hydrolysis, photolysis, aquatic and soil metabolism, terrestrial dissipation) are routinely conducted for all outdoor use pesticides. Other studies (e.g., photodegradation in air, which is seldom requested because of study design issues, volatility, and spray drift) are conditionally required and are triggered by use or application patterns and basic product chemistry data. The Agency regulations found in 40 CFR 158.29 (Support Document #29) describes the types and amounts of data that the Agency needs for assessing the environmental fate of an active ingredient. The types of data may vary, depending on where the pesticide is used. Examples of guidance for reviewing studies is provided in Subdivision N Guidelines and the SEPs (Support Documents #5 and #6.).

OPP also may review sources of data other than those conducted according to the Subdivision N Guideline studies, such as non-guideline studies submitted by the pesticide registrant and published scientific literature. It is important to note that the manner in which additional non-guideline data are incorporated into a risk assessment is established on a case-by-case basis. The risk assessment team uses professional judgement in evaluating such aspects as

- The data quality objectives of the study,

- Availability of documentation sufficient for evaluating the technical merit of the methods and results analysis, and
- General applicability of the results as compared to the exposure scenarios that are considered important in the risk assessment.

Non-guideline data may be used to address data gaps in the assessment, even to the extent of providing quantitative values for dissipation pathway inputs for exposure modeling. This data may even be useful for addressing fate issues which are not specifically identified in the existing guideline studies. Data from non-guideline studies may considered supplemental but can not be used to satisfy guideline requirements to support registration.

Controlled environmental fate laboratory studies are used to determine the persistence, mobility, and bioconcentration potential of a pesticide and its major degradates. Persistence studies assess what happens to a pesticide when it interacts with water, soil, air, and sunlight. Mobility studies attempt to predict the potential of the pesticide to volatilize into the atmosphere, move into ground or surface waters, or bind to the soil. And bioconcentration studies evaluate the potential of a pesticide to partition to aquatic biota and the degree to which bioconcentration can be reversed should external exposure to the pesticide or degradates be reduced or eliminated. These studies are designed to help characterize how a pesticide chemical dissipates once it is released into the environment, and identify the significant degradates likely to result from these processes.

Degradation studies include hydrolysis, photodegradation in water, photodegradation in air, and photodegradation on soil. The hydrolysis study determines the potential of the parent pesticide to degrade due to the influence of water alone. Photodegradation studies determine the potential of the parent pesticide to degrade in water, soil, or air as it interacts with sunlight. During these studies, data are also collected concerning the identity, formation and persistence of significant degradates.

Metabolism studies include aerobic soil metabolism, anaerobic soil metabolism, anaerobic aquatic metabolism, and aerobic aquatic metabolism. The soil microbial metabolism and hydrolysis studies determine the persistence of the pesticide when it interacts with soil microorganisms under aerobic and anaerobic conditions. The aquatic metabolism studies produce similar data that are generated by pesticide interaction with microorganisms in a water/sediment system. These studies also identify the significant degradates that result from biological degradation.

Mobility studies, which include leaching, adsorption/desorption, and volatility, provide information on the mode of transport and eventual destination of the pesticide in the environment.

Bioconcentration studies in aquatic organisms are used to estimate the potential of a pesticide, under controlled laboratory conditions, to partition to the organisms due to respiratory

and dermal exposures. These studies also provide information on the degree to which bioconcentration of a pesticide or degradate can be reversed should levels in the surrounding aquatic environment be reduced.

Field studies which identify the environmental dissipation processes, assess the transformation, transport, and fate of pesticides under actual use conditions at representative field sites. These studies characterize the relative importance of each route of dissipation of the pesticide and its major degradates. Data generated from field dissipation studies can provide more realistic estimates (albeit limited in time and space) of the persistence and transport of a pesticide and its degradates when the parent pesticide is applied under actual use conditions.

Once the individual studies are reviewed and determined to be appropriate for inclusion in the risk assessment, OPP relies on the results of these studies to provide the quantitative fate and transport inputs for ecological exposure modeling. The selection of input values are specific to the exposure model being employed and Support Documents #9, #?, and #? provide the risk assessment team with guidance necessary for the selection process. Discussions of the exposure modeling methods available to OPP for screening level risk assessments are presented in the following sections.

b. Evaluation of Uncertainties (To be completed.)

c. Aquatic Organism Exposure Modeling

For aquatic organisms, such as fish and invertebrates, OPP usually estimates exposure by the use of computer simulation models. These models calculate estimated environmental concentrations (EECs) in surface water using laboratory data that describe how fast the pesticide breaks down to other chemicals and how it moves in the environment. A tiered approach is used to estimate environmental concentrations, which utilizes the Tier 1 screening model GENEEC2 (GENeric Estimated Environmental Concentration) and higher tiered screening models, such as PRZM-EXAMS (Pesticide Root Zone Model - Exposure Analysis Modeling System). More detailed descriptions of these models can be found on EPA's website at the following url: www.epa.gov/pesticides/oppefed1/models. When reliable surface water monitoring data is available, EPA uses it to help characterize the levels of pesticide that are being detected in the environment. If monitoring data shows higher confirmed detections than estimated by modeling, the higher monitoring values may be used in the risk assessment and a re-evaluation of the model input parameters may be initiated to explore the impact of selected input values on the model output.

GENEEC2 provides a rapid screen to separate the low risk pesticides from those that need more refined assessments. The model estimates high level exposure values of pesticides in surface water using the following inputs: basic chemical characteristics, pesticide label use and application information, adsorption of the pesticide to soil or sediment, direct deposition of spray

drift into the water body, and degradation of the pesticide in soil before runoff and within the water body. It is a single event model, meaning that it assumes one single large rainfall/runoff event occurs on a 10-hectare field and removes a large quantity of pesticide at one time from the field to a pond which has a 20,000 L water volume and is 2-meter deep. GENEEC2 is expected to overestimate pesticide concentrations in surface water for most sites because it uses maximum pesticide application rates, assumes that no buffer exists between the pond and the treated field, simulates runoff from a 6-inch rainfall over a 24-hour period, and assumes that the entire watershed is cropped and the pesticide is applied to the entire crop. See the GENEEC2 User's Manual and GENEEC2 Model Description for more information (Support Document XXX).

PRZM-3 and EXAMS II are used for a higher level, refined (Tier 2) estimation of pesticide concentrations in surface waters for aquatic exposure characterization (Support Documents #10 and #11). These values are still screens, albeit finer screens than GENEEC2.

PRZM is a process or "simulation" model that calculates what happens to a pesticide in a farmer's field on a day-to-day basis. It considers factors, such as rainfall and plant transpiration of water, as well as how and when the pesticide is applied. It has two major components: hydrology and chemical transport. The hydrologic component for calculating runoff and erosion of soil is based on the Natural Resource Conservation Service curve number technique and the Universal Soil Loss Equation. Evapotranspiration of water from the root zone of the soil profile is estimated either directly from pan evaporation data or is based on an empirical formula. Total evapotranspiration of water includes evaporation from crop interception, evaporation from soil, and transpiration by the crop. Water movement is simulated by the use of generalized soil parameters, including field capacity, wilting point, and saturation water content. The chemical transport component can simulate pesticide application on the soil or on the plant foliage. Dissolved, adsorbed, and vapor-phase concentrations in the soil are estimated by simultaneously considering the processes of pesticide uptake by plants, surface runoff, erosion, decay, volatilization, foliar washoff,, and sorption. Each PRZM modeling scenario represents a unique combination of climatic conditions, crop specific management practices, soil specific properties, site specific hydrology, and pesticide specific application and dissipation processes. Each PRZM simulation is conducted using up to 36 years of rainfall data to cover year-to-year variability in runoff. PRZM-3 allows the user to consider pulse loads and predict peak events. Daily edge-of-field loadings of pesticides dissolved in runoff waters and sorbed to sediment, as predicted by PRZM, are discharged into a standard water body ("standard pond" for ecological assessments) simulated by the EXAMS model.

EXAMS II is also a process model, but it simulates the processes that occur in the water body rather than on the agricultural field. EXAMS II takes the runoff and spray drift loadings generated by PRZM and estimates the concentration in the pond on a day-to-day basis. It accounts for volatilization, sorption, hydrolysis, biodegradation, and photolysis of the pesticide in the aquatic environment. Since EXAMS is a steady-state model, the water bodies are modeled as having constant volume. Multiple-year pesticide concentrations in the water column are

calculated from the simulations as the annual daily peak, maximum annual 96-hour average, maximum annual 21-day average, maximum annual 60-day average, and annual average. The 1 in 10 year maximum values for each averaging period are used to calculate risk quotients.

In order to improve the confidence level of these models, scientists in OPP are working with the modeling community through the Exposure Modeling Work Group (EMWG) and with EPA's Office of Research and Development (ORD) to validate the performance of these models in the field at the intended scale. In addition, OPP released an input parameters selection manual which provides guidance in selecting input values when using these models. (See Support Document #9.)

For pesticides that are currently on the market, water monitoring data may be available. Data from water monitoring studies may be available from EPA databases, USGS NAWQA, and industry, state and university studies. These data can be evaluated on a case-by-case basis to determine the likelihood, extent, and nature of pesticide concentration in water under current use practices and actual field conditions. The risk assessment team considers such study aspects as the points and frequency of sample collection, the analyte suite, and detection limits determining how such data will be incorporated into the risk assessment. Since monitoring does not necessarily target pesticide use areas or the time of year when pesticide concentrations may be at their peak. Therefore, it does not necessarily provide a reliable estimate of acute exposure because sampling may not occur where and when the highest concentrations of a pesticide would occur.

d. Terrestrial Organism Exposure Modeling

The focus of terrestrial wildlife exposure estimates is on birds and mammals. For exposure to terrestrial organisms, such as birds and small mammals, OPP mostly looks at the residues of pesticides on food items and assumes that organisms are exposed to a single pesticide residue in a given exposure scenario. Two approaches are used for estimating exposure to terrestrial wildlife, which are dependent on the application method: (1) spray applications and (2) granular, bait, and treated seed applications.

For spray applications, estimation of pesticide concentrations in wildlife food items focuses on quantifying possible dietary ingestion of residues on vegetative matter and insects. The residue estimates are based on a nomogram that relates food item residues to pesticide application rate. The nomogram is based on an EPA database called UTAB (Uptake, Translocation, Accumulation, and Biotransformation, a compilation of actual measured pesticide residue values on plants) and work from Fletcher et al. (Support Document #15). Residues may be compared directly with dietary toxicity data or converted to an oral dose, as is the case for small mammals. The first tier of the nomogram uses the maximum predicted residues. Subsequent refinements may consider mean residues. However, maximum residue values are used in the screening level assessments for endangered species. Residues may be converted

directly with dietary toxicity data or converted to an oral dose (e.g., for small mammals). For mammals, the residue concentration is converted to daily oral dose based on fractions of body weight consumed daily as estimated through mammalian allometric relationships in EPA's Wildlife Exposure Factors Handbook (Support Document #33)

For granular, bait, and treated seed applications, estimation of loadings of pesticide per unit area are calculated (suitable for granular, bait, and treated seed applications). This approach considers observed effects in field studies and relates them to pesticide applied to surface area. It is intended to represent exposure via multiple routes and not just direct ingestion. The label rate of application for the active ingredient is the basis for the exposure term. The amount of pesticide per square foot is calculated. In-furrow applications assume 1% of granules, bait, or seed are unincorporated. Banded treatments assume that 15% of granules, bait, seeds are unincorporated. Broadcast treatment without incorporation assumes 100% of granules, bait, seeds are unincorporated.

e. Non-Target Plant Exposure Modeling

Exposure for non-target aquatic plants is assessed in a manner consistent with exposure for other aquatic organisms. (See previous section on Aquatic Organism Exposure).

Terrestrial and semi-aquatic plant exposure characterization employs runoff and spray drift scenarios contained in OPP's Terrplant model (Support Document #18). Exposure calculations are based on a pesticide's water solubility and the amount of pesticide present on the soil surface and within the first inch of depth. For dry areas, runoff is characterized as "sheet runoff" from a treated acre to an adjacent non-target area; for semi-aquatic (wetland) areas, runoff is characterized as "channel runoff" from ten treated acres to a distant, low-lying, non-target acre. Default spray drift assumptions are one percent for ground applications and five percent for aerial, airblast, forced air, and chemigation applications.

2. Effects Characterization

An ecological effects characterization describes the types of effects a pesticide can produce in an organism and how those effects change with varying pesticide exposure levels. This characterization is based on an effects profile that describes the available effects (toxicity) information for various plants and animals and an interpretation of available incidents information and effects monitoring data. Environmental fate data, monitoring data, and computer models are used to estimate the exposure of non-target animals and plants to pesticide residues in the environment.

40 CFR Parts 158.490, 158.540, and 158.590 specifies the types and amounts of data that the Agency needs to determine the risks of a pesticide to wildlife, aquatic organisms, and plants. The types of data needed may vary depending on where the pesticide is used. A list of the studies

that the Agency may require in support of the registration or approval of certain pesticides is provided in Support Document #29. In these tests, organisms are exposed to different amounts of pesticides and their responses to these varying concentrations are measured. Study endpoints are used to estimate the toxicity or hazard of a pesticide. (See Support Document #? for toxicity categories). The toxicity testing scheme is a tiered one in which results from a lower level study are used to determine potential harmful effects to non-target organisms and whether further testing is required. Depending on the results of the studies, testing can progress from basic laboratory test in the lowest level to applied field tests in the highest level.

Other data sources (e.g., ecotoxicity databases, open literature) can also be used to support the characterization. Since this information is typically not collected using the Agency's test guidelines it is considered supplemental information.

C. Risk Characterization

Risk characterization is the integration of effects and exposure characterization to determine the ecological risk from the use of the pesticide and the likelihood of effects on aquatic life, wildlife, and plants based on varying pesticide use scenarios.

Agency policy requires that risk characterizations be prepared in a manner that is clear, transparent, reasonable, and consistent with other risk characterizations of similar scope.

The risk assessor integrates the effects and exposure characterizations to determine the risk from the use of the pesticide to aquatic life, wildlife, and plants based on varying pesticide use scenarios.

1. Integration of Exposure and Effects Data (The Risk Quotient)

Risk characterization integrates the results of exposure and toxicity data to evaluate the likelihood of adverse ecological effects on non-target species. For most chemicals, the effects characterization is based on a deterministic approach using one point on a concentration-response curve (e.g., LC50). In this approach, OPP uses the risk quotient (RQ) method to compare exposure over toxicity. Environmental concentrations (EECs), based on maximum application rates, are divided by acute and chronic toxicity values. (Equations provided in Support Document #8).

2. Levels of Concern (The Policy Tool for Interpreting RQs)

After risk quotients are calculated, they are compared to the Agency's Levels of Concern (LOCs). These LOCs are the Agency's interpretative policy and are used to analyze potential risk to non-target organisms and the need to consider regulatory action. These criteria are used to indicate when a pesticide use as directed has the potential to cause adverse effects on non-target

organisms. LOCs currently address the following risk presumption categories:

acute : High potential for acute risk to non-target organisms which may warrant regulatory action in addition to restricted use classification;

acute restricted use: Potential for acute risk to non-target organisms, but may be mitigated through restricted use classification;

acute endangered species: Endangered species may be adversely affected by use; and

chronic risk: Potential for chronic risk may warrant regulatory action.

It should be noted that both acute endangered species and the chronic risk LOCs are considered in the screening-level assessment of pesticide risks to endangered species.

The history and background of the LOCS is helpful in understanding how the LOCs are currently used. LOCs can be traced back to 1975 and the regulatory risk criteria in the regulations for the enforcement of FIFRA (40 CFR 129: 28260-28265; 28281-28284) and in the Special Review of Pesticides: Criteria and Procedures: Final Rule (40 CFR 154: 49005; 49007; 49016 § 154.7(a)(3),(4), (5), and (6)).

In 1975 'Safety factors' of 5 for birds and mammals and 10 for aquatic organisms were used to establish "safe" levels for non-target species. These factors were used to establish 'Restricted Use' triggers. That is, exposure levels exceeding toxicity thresholds by factors >0.2 or 0.1 and <1.0 or 0.5 which placed a chemical into a potential Special Review category. The interpretation of these safety factors was as follows:

- RQ below 0.2 or 0.1 - Acceptable exposure compared to toxicity,
- RQ< 1.0 or 0.5 - Careful use may limit effects on non-target organisms to acceptable levels, and
- RQ > 1.0 or 0.5 - Risks were at sufficient level to warrant consideration of risks versus benefits.

A mathematical exploration of the interpretation of safety factors as applied to median lethal dose estimates and selected dose response relationships is presented on pages 3 and 4 of Support Document #8.

In 1986, the1975 safety factors were incorporated into the OPP's Standard Evaluation Procedure: Ecological Risk Assessment (Support Document #8). Although these safety factors were now applied in a manner similar to how they are used today, they were not yet termed LOCs.

By 1992, the Assistant Administrator for OPP made the use of the term official policy (Support Document #25). In this document, the safety factors were used to establish a pesticide classification:

- High acute concern LOC is an EEC> 0.5 X LC50 or LD50;
- Restricted use pesticide LOC is an EEC > 0.1 X LC50 for aquatic life or EEC> 0.2 X LD/50 for birds; and
- Chronic LOCs for aquatic life and birds were set at a threshold where the EEC exceeded the Lowest Observed Effect Concentration or Level (LOEC or LOEL) established from the chronic exposure toxicity tests.

Under this statement of policy, no LOCs for endangered species were established.

In 1993, OPP's Director released the Implementation Paper for the New (risk) Paradigm (Support Document #31). This implementation plan reiterated the LOCs for acute high concern and restricted use pesticide classifications as they are used today. It repeated the establishment of chronic effects LOCs based on the use of the LOEC or LOEL. In addition, the Implementation Paper established that the criteria to determine if a pesticide may affect listed endangered species as outlined in Support Document #8.

In 1994, OPP released a memorandum on the interpretation of the LOC and its use (Support Document #26). This document states that when the RQ exceeds the LOC for a particular category, "risk to that particular category is presumed to exist". The risk presumptions associated with various LOCs are as follows:

- Acute RQ > 0.5 (aquatics, mammals, birds) - presumption of high acute risk
- Acute RQ > 0.1 (aquatics) or 0.2 (mammals and birds - risks may be mitigated through restricted use
- Acute RQ > 0.05 (aquatics) or 0.1 (mammals and birds) - endangered species may be affected acutely
- Chronic RQ > 1 - presumption of chronic risk, endangered species my be affected chronically
- Non- endangered plant RQ >1 - presumption of high risk
- Endangered plant RQ > 1 - endangered plants may be affected

It is noteworthy that the toxicity endpoints for animal chronic RQs in the above set of LOCs are based on the no observed effect level (NOEL) for mammal and birds. For aquatic organisms the policy statement allows either the NOEL or the geometric mean of the NOEL and LOEL to be used as the basis for aquatic organism RQs. In 1999, a policy was established regarding calculation of aquatic chronic RQs (use of the NOEC only), but did not change the LOCs to which they are compared.

3. Comparison of Field and Laboratory Data

Given the general widespread nature of pesticide uses and the variability in the physical, chemical, and biological conditions associated with pesticide use sites, validation of the results of the existing screening risk assessment process would be impractical. However, OPP does consider data on exposure and effects collected under field conditions to make determinations on the predictive utility of the screening assessment.

OPP routinely receives information on the field dissipation of pesticides under actual use conditions. These data provide the Agency with information on the persistence of the parent compound and the rate of production of degradates. Incorporation of the results of field dissipation data into the quantitative exposure modeling is problematic due to the nature of the model input requirements. However, overall rates and routes of pesticide decline as predicted by the fate models can be examined and compared with the results of the field dissipation models to determine the degree of conservatism in the risk assessment fate modeling.

In addition to field dissipation measurements, scientists often consider available data on environmental media monitoring for pesticides. For example, the results of the screening environmental models are compared with monitoring data for surface waters. However, there are practical limitations to surface water monitoring efforts. For example non-targeted routine monitoring programs, such as the U.S. Geological Survey's NAWQA, are more useful for tracking trends than they are for establishing true peak concentrations. However, comparison of the Agency modeling results with such monitoring programs can provide some insight into the degree to which modeling results reflect realistic conditions in the field.

After the Ecological, Fate, and Effects Task Force review, the Agency no longer required avian and aquatic guidelines field testing, except in unusual circumstances (Support Document #25). However, when field studies along with incident data reports and compliance monitoring studies are availble, they will be used to help elucidate the potential sources and magnitude of uncertainties when extrapolating from effects predictions based on laboratory toxicity data to effects occurrence in the field. As pointed out in the Agency's Guidelines for Ecological Risk Assessment (Support Document #7), developing solid relationships between cause and observed field effects adds to the certainty of the assessment. The criteria presented in these guidelines adopted from Fox (1991) and similar to other criteria reviewed by Fox (U.S. Department of Health, Education, and Welfare 1964, Hill 1965, and Susser 1986a, 1986b), stressed the importance of the strength of association between the causative agent and the observed effect.

As discussed for surface water monitoring, field effects data are limited in the ability to account for the myriad combinations of physical, chemical, and biological variables that might affect organism response to pesticides in the environment. Consequently, field studies or incident reports cannot conclusively validate screening risk assessment predictions, but they can allow inferences on the reasonableness of the assessment predictions.

Incident monitoring usually provides limited information for an ecological assessment because most incidents are not reported and those that are reported often do not have enough information to correlate cause and effect. Generally, it is assumed that the application was from normal use and was applied within the rates allowed on the label unless otherwise indicated. On occasion, the use rates are reported in incident investigations, but actual documentation with scientific rigor is rare. Therefore, incident reports often provide limited information about the correlation between use rates and effect levels. However, in general, the greater the number of wildlife kill incidents and the greater the number of individuals involved, the higher the confidence that risks are associated with the pesticides use.

4. Description of Assumptions, Uncertainties, and Strengths and Limitations of the Assessment (To be completed.)

5. Discussion of Predictive Ability of Screening Assessment (To be completed.)

6. Conclusions (To be completed.)

VII. Future Directions (To be completed.)

VIII. List of Support Documents

#1. Study Classifications Used by EFED in Data Evaluation Records (DER's) dated February 26, 2003

#2. Pesticide Assessment Guidelines, Subdivision E, Hazard Evaluation: Wildlife and Aquatic Organisms; EPA-540/9-82-024, October 1982

#3. Pesticide Assessment Guidelines, Subdivision J, Hazard Evaluation: Nontarget Plants; EPA-540/09-82-020, October 1982

#4. Pesticide Assessment Guidelines, Subdivision L, Hazard Evaluation: Nontarget Insects; EPA-540/9-82-019, October 1982

#5. Pesticide Assessment Guidelines, Subdivision N, Chemistry: Environmental Fate; EPA-540/9-82-021, October 1982

#6. List of OPP's Standard Evaluation Procedures Available for Ecological and Environmental Fate Guideline Studies

#7. Guidelines for Ecological Risk Assessment. Risk Assessment Forum. EPA/630/R-95/002F, April 1998

#8. Hazard Evaluation Division. Standard Evaluation Procedure. Ecological Risk Assessment. EPA-540/9-85-001, June 1986.

#9. US EPA OPP EFED Guidance for Selecting Input Parameters in Modeling the Environmental Fate and Transport of Pesticides. Version II. February 28, 2002

#10. PRZM Standard Crop/Location Scenarios, Procedure to Develop and Approve New Scenarios, and PRZM Turf Modeling Scenarios to Date. Memorandum from EFED's acting Director, February 27, 2002.

#11. Pesticide Root Zone Model (PRZM) Field and Orchard Crop Scenarios: Standard Procedures for Conducting Quality Control and Quality Assurance

#12. Policy for Estimating Aqueous Concentrations from Pesticides Labeled for Use on Rice. Memorandum from EFED's Acting Director, October 29, 2002.

#13. Mammalian Risk Assessments. February 23, 1995 Draft.

#14 Hoerger, F. and E.E. Kenaga. "Pesticide Residues on Plants: Correlation of Representative Data as a Basis for Estimation of Their Magnitude in the Environment".

#15. J.S. Fletcher, J.E. Nellessen and T.G. Pfleeger. 1994. Literature Review and Evaluation of the EPA Food-Chain (Kenaga) Nomogram, an Instrument for Estimating Pesticide Residues on Plants. Environ. Tox. Chem. 13(9): 1383-1391.

#16. Calculation of Terrestrial EECs. EFED Policy Memorandum from EFED Acting Director, August 26, 1999.

#17. Documentation for ELL-Fate Version 1.2, July 19, 2001.

#18. Automation of Environmental Exposure Concentrations (EECs) and Determinations of Risk Quotients (RQs) for Terrestrial Plants Using TerrPlant Model, Version 1.0. EFED Policy Memorandum from EFED Acting Director, October 16, 2002.

#19. Closure on Nontarget Plant Phytotoxicity Policy Issues. Memorandum from EEB/EFED Chief, October 21, 1994.

#20. Comparative Analysis of Acute Avian Risk from Granular Pesticides. US EPA OPP, March 1992.

#21. Guidance for Conducting Screening Level Avian Risk Assessment for Spray Applications of Pesticides. US EPA OPP, July 7, 2000.

#22. EIIS. Documentation for the Ecological Incident Information System. EFED Information and Support Branch, EFED, OPP. August 15, 2002.

#23. Guidance Document for Conducting Terrestrial Field Studies. EPA 540/09-88-109, September 1988.

#24. The Office of Pesticide Programs' Guidance Document on Methodology for Determining the Data needed and the Types of Assessments Necessary to Make FFDCA Section 408 Safety Determinations for Lower Toxicity Pesticide Chemicals. OPP US EPA, May 9, 2002.

#25. Decisions on the Ecological, Fate, and Effects Task Force. Memorandum from US EPA Assistant Administrator to Director of US EPA OPP, October 29, 1992.

#26. What the LOC is, and How it Should Be Used. Memorandum from EEB Chief, June 8, 1994.

#27. Format and Risk Characterization. Additional Guidance for EFED Risk Assessment Documents. Draft EFED SOP, October 17. 2001.

#28. Science Policy Council Handbook. Risk Characterization. EPA 100-B-00-002, December 2000.

#29. US EPA 40 CFR Part 158 Data Requirement Tables

#30. Science Policy Council Handbook. Peer Review. EPA 100-B-00-001, December 2000.

#31. Implementation Paper for the New Paradigm. Memorandum from OPP Office Director, August 25, 1993.

#32. Pesticide EcoToxicity Database.

#33. Wildlife Exposure Factors Handbook. Table of Contents and Introduction.

(To be completed.)

	FIFRA	ESA	surmountable / insurmountable
effects standard	unreasonable adverse (includes economic, social + environmental costs)	adverse effect	insurmountable
data	- provided by registrants - limited by CFR part 158	best available	surmountable – - broader lit search - requiring additional data from registrants - more info on incidents (monitoring) - broader types of evaluations
emergency/ unregistered use (section 18)	- extensive list of emergency situations	acts of god	
problem formulation for risk assessment	- management perspective looms heavily on goal + approach	- goal taking at risk of pesticide use on essential bio requirements of T+ Species	surmountable - for T+ species utilize FIFRA EPA guidance + focused